Interpretive Guidelines for Standards of Care Determinations

These standards of care interpretive guidelines have been developed to assist hospital and ambulatory surgical center risk managers, and others who fall under the Kansas risk management statutes and regulations, in their deliberations when reviewing quality of care issues. These guidelines provide examples of events which fall under each standard of care level and will assist those who complete risk management documentation for internal and external use. The examples listed below are not all inclusive of clinical events which may take place in a facility. These guidelines, written by the Kansas Association of Risk and Quality Management and the Kansas Hospital Association, have been approved by the Kansas Department of Health and Environment.

Kansas Administrative Regulation 28-52-4

K.A.R. 28-52-4. Standard-of-care determinations. (a) Each facility shall assure that analysis of patient care incidents complies with the definition of a "reportable incident" set forth at K.S.A. 65-4921. Each facility shall use categories to record its analysis of each incident, and those categories shall be in substantially the following form:

(1) Standards of care met;
(2) standards of care not met, but with no reasonable probability of causing injury;
(3) standards of care not met, with injury occurring or reasonably probable;
(4) possible grounds for disciplinary action by the appropriate licensing agency.

(b) Each reported incident shall be assigned an appropriate standard-of-care determination under the jurisdiction of a designated risk management committee. Separate standard-of-care determinations shall be made for each involved provider and each clinical issue reasonably presented by the facts. Any incident determined by the designated risk management committee to meet category (a)(3) or (a)(4) shall be considered a ``reportable incident'' and reported to the appropriate licensing agency in accordance with K.S.A. 65-4923.

(c) Each standard-of-care determination shall be dated and signed by an appropriately credentialed clinician authorized to review patient care incidents on behalf of the designated committee. In those cases in which documented primary review by individual clinicians or subordinate committees does not occur, standard-of-care determinations shall be documented in the minutes of the designated committee on a case-specific basis. Standard-of-care determinations made by individual clinicians and subordinate committees shall be approved by the designated risk management committee on at least a statistical basis. (Authorized by and implementing K.S.A. 65-4922; effective Feb. 27, 1998.)

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(1) Standards of care met.

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(1) Standards of care met, even if an injury occurred to the patient. Care provided met the standards of care.

Examples:

- Patient found on the floor; all **appropriate** precautions were in place, i.e., call light in place, non-skid footwear in use, etc.
- Patient given medication and had an allergic reaction, patient had been asked allergy history. Allergy bracelet was checked. Medication given was not listed as an allergy.
- Patient presents to ED with fever. Antibiotics started. Patient returns 48 hours later and is placed on a new medication due to change in condition.
- Patient and/or family manipulated equipment after being told to keep their hands off the equipment.
- A patient with no identified allergies has an allergic reaction to a prescribed medication.

(2) Standards of care not met, but with no reasonable probability of causing injury.

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(2) Standards of care not met, but with no reasonable probability of causing injury.

No reasonable probability means may be possible but is not probable.

Injury is defined to mean an incident that requires significant medical intervention, or causes disability or death.

Significant medical intervention may include a more intensive level of care, surgical intervention, significant change in medications and/or increased length of stay due to unexpected additional diagnostic or treatment measures.

Examples:

- Patient was given the wrong medication. Medication administration process was not followed. Minor medical intervention needed. Minor medical intervention could be provided by a healthcare provider, for example: nurse, physician, allied health, etc.
- Patient at risk for falls fell out of bed **resulting in some bruising**. Fall precautions were not implemented.

- A near miss occurred when a pharmacist dispensed the wrong medication and the nurse caught the error before the medication was administered.
- Physician orders indicated patient was to ambulate only with assistance. Patient was allowed to get up and was not accompanied as ordered. Patient fell, sustaining minor laceration to knee.
- Walking shoes as ordered by the physician were not placed on the patient during ambulation training with walker. Patient stubbed a toe causing an abrasion. Abrasion was cleansed and ointment applied.
- Incorrect medication dispensed by pharmacy and administered to the patient. No harm occurred to the patient and there was no reasonable probability of harm.
- Critical lab value results were not reported to the physician. There were no changes in patient management when discovered.

(3) Standards of care not met, with injury occurring or reasonably probable.

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(3) A **reportable standard of care not met** means a deviation from the standard of care that has a known and direct adverse outcome / impact on patient care *and* causes injury or there is a **reasonable probability** (more likely than not) of causing injury to that patient.

Injury is defined to mean an incident that requires significant medical intervention, or causes disability or death.

Significant medical intervention may include a more intensive level of care, surgical intervention, significant change in medications and/or increased length of stay due to unexpected additional diagnostic or treatment measures.

Examples:

- Following incorrect medication administration during surgery, patient suffers neurological damage.
- Patient is given a medication for which they have a stated allergy and patient experiences severe anaphylactic reaction.
- Orders for a confused, combative patient stated the patient was to have 1:1 care while the patient was up in the chair. After the patient was assisted to the chair, the assigned caregiver left the room. While the caregiver was gone, the patient fell from the chair and fractured a hip.
- Failure to report significant changes in patient condition, causing patient injury.
- Failure of healthcare provider to respond to significant changes in patient condition, causing patient injury.
- Critical lab value results were not reported to physician with reasonable probability of injury.

(4) Possible grounds for disciplinary action by the appropriate licensing agency.

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(4) A **reportable** incident with possible grounds for disciplinary action by the appropriate licensing agency.

Examples:

- Practicing without a current license.
- Working under the influence of drugs/alcohol.
- In the course of providing patient care, healthcare worker is verbally abusive.
- Trended incidents identifying quality or performance issues.
- Violations of a licensing agency's disciplinary codes.
- Falsification of the medical record.
- Practicing outside the scope of one's license.
- Drug diversion.
- Theft of hospital/patient property by staff member.
- Intentional viewing of a patient's protected health information by a staff member or physician without authorization.
- Willful discussion of a patient's protected health information by a staff member or physician without authorization.

NCI – Non-Clinical Incident. Used for internal trending purposes. Does not meet requirements for reporting to regulatory agencies.

Examples:

- Theft of hospital or personal property by non-staff persons.
- Lost patient articles, i.e., watch, ring, etc.
- Visitor closes door on finger.
- Visitor falls in parking lot.

Resources

A. JCAHO Sentinel Event Policy and Procedures, Oregon Association of Hospitals and Health Systems
B. JCAHO, January 25, 2006, Sentinel Event Alert
C. Florida Statute 766.102 Medical Negligence: Injury
D. General Information for Panel Members: Utah, Division of Occupational & Professional Licensing A3. Proximate Cause
E. Robert I. Simon, MD Commentary: Medical Errors, Sentinel Events, and Malpractice, Journal of American Academy of Psychiatry Law 34:99-100, 2006

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